IV. FDA'S ASSERTION OF JURISDICTION OVER CIGARETTES AND SMOKELESS TOBACCO AT THIS TIME IS JUSTIFIED

The Food and Drug Administration (FDA) has always exercised jurisdiction under the Federal Food, Drug, and Cosmetic Act (the Act) over tobacco products when there was evidence that these products were "intended" to treat or prevent disease or to affect the structure or function of the body. As discussed in section II.E., above, the Agency may consider relevant evidence from any source in determining whether a product is intended as a drug or device. On previous occasions when the Agency has been asked to consider whether tobacco products were within its jurisdiction, however, there was insufficient evidence to conclude that tobacco products were intended to affect the structure or function of the body, except where the manufacturer expressly promoted a tobacco product for use in treating disease or affecting the structure or function of the body.

Since the last occasion on which FDA considered whether to assert jurisdiction over tobacco products without claims, the state of the evidence has changed dramatically. A wealth of new evidence has become available demonstrating that: (1) the ability of nicotine in cigarettes and smokeless tobacco to produce addiction and other significant pharmacological effects is widely known and therefore foreseeable to a reasonable tobacco manufacturer; (2) consumers use cigarettes and smokeless tobacco predominantly to obtain the pharmacological effects of nicotine; and (3) previously undisclosed statements, research, and actions of tobacco manufacturers demonstrate that they intend their products to be used as nicotine delivery devices. As described in section II., above, FDA has determined that this evidence establishes that cigarettes and smokeless tobacco are

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"intended to affect the structure or any function of the body" within the meaning of the Act's "drug" and "device" definitions. FDA has therefore revised its position and concluded that all currently marketed cigarettes and smokeless tobacco are in fact "intended to affect the structure or any function of the body" and therefore are within its jurisdiction.

Information developed since 1980 also demonstrates that for most people tobacco use and nicotine addiction begin in childhood and adolescence. The data now suggest that if children and adolescents can be prevented from initiating tobacco use, they are unlikely to begin tobacco use later in life, thereby preventing the onset of tobacco-related disease and premature death. Before the importance of youth-centered interventions was identified, most of the regulatory approaches available under the Federal Food, Drug, and Cosmetic Act to address tobacco-related disease and death, such as removal of the products from the market, were not believed to be feasible. The new information that nicotine addiction is a pediatric disease provides an additional basis to conclude that restricting the sale, distribution, and use of cigarettes and smokeless tobacco to people under the age of eighteen is an effective tool to reduce the adverse health consequences of tobacco use. Thus, asserting jurisdiction over cigarettes and smokeless tobacco now presents an opportunity to use the Agency's resources efficiently for substantial public health gains.

Several comments maintain that the Agency is not permitted to change its earlier interpretation of the Act. However, it is a well-established principle of administrative law that an Agency may revise its interpretation or application of a statute if it supplies a reasoned explanation for its changed interpretation or position. *See Action on Smoking*

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and Health v. Harris (ASH), 655 F.2d 236, 242, n.10 (D.C. Cir. 1980) (recognizing that FDA is permitted to modify its earlier position on tobacco products and that the new position would be accorded deference by the courts); *see also Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 57 (1983); *Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 862 (1984); *Rust v. Sullivan*, 500 U.S. 173, 186-187 (1991); *Smiley v. Citibank, N.A.*, 116 5. Ct. 1730 (1996). Indeed, an agency is expected to reevaluate the wisdom of its interpretations and make changes in those interpretations when warranted by current knowledge and circumstances. *Rust*, 500 U.S. at 186-187. In *Rust*, the Court explained as follows:

> This Court has rejected the argument that an agency's interpretation is not entitled to deference because it represents a sharp break with prior interpretations of the statute in question. In *Chevron*, we held that a revised interpretation deserves deference because an initial agency interpretation is not instantly carved in stone and the agency, to engage in informed rule making, must consider varying interpretations and the wisdom of its policy on a continuing basis. An agency is not required to establish rules of conduct to last forever, but rather must be given ample latitude to adapt its rules and policies to the demands of changing circumstances.

Id. (citations and internal quotation marks omitted); *see also American Trucking Ass'ns v. Atchison, Topeka, and Santa Fe Ry. Co.*, 387 U.S. 397 (1967) (an agency, "faced with new developments or in light of reconsideration of the relevant facts and its mandate, may alter its past interpretation and overturn past administrative rulings and practice"). The new evidence presented in the Jurisdictional Analysis and in section II., above, provides a reasoned basis for FDA's change in position on the applicability of the Act to cigarettes

and smokeless tobacco without claims. In this section, FDA describes its earlier decisions on whether to regulate particular tobacco products and reviews the new evidence that now supports the Agency's assertion of jurisdiction over cigarettes and smokeless tobacco.

A. FDA HAS ALWAYS EXERCISED AUTHORITY TO REGULATE TOBACCO PRODUCTS WHEN THE EVIDENCE ESTABLISHED THAT THEY FELL WITHIN THE DRUG OR DEVICE DEFINITIONS

FDA's assertion of jurisdiction over tobacco products is not new. For more than 80 years FDA has taken the position that it has jurisdiction over tobacco products that fall within the Act's definitions of regulated products. As early as 1914, the Agency claimed jurisdiction to regulate tobacco products labeled *or used* for "medicinal purposes."[1160] In the succeeding decades, FDA brought and won enforcement actions against cigarettes that were intended to treat or prevent disease or to affect the structure and function of the body. *See, e.g., United States v. 354 Bulk Cartons . . . Trim Reducing-Aid Cigarettes*, 178 F. Supp. 847, 851 (D.N.J. 1959) (cigarettes claimed to reduce weight were intended to affect the structure or function of the body); *United States v. 46 Cartons, More or Less, Containing Cigarettes*, 113 F. Supp. 336, 338-339 (D.N.J. 1953) (cigarettes claimed to

[1160] The predecessor to FDA issued the following statement about its jurisdiction over tobacco: "Tobacco and its preparations, when labeled in such a manner as to indicate their use for the cure, mitigation, or prevention of disease, are drugs within the meaning of the act, and, as such, are subject to the provisions thereof. . . . On the other hand, tobacco and its preparations which are not so labeled *and are used for smoking or chewing or as snuff and not for medicinal purposes* are not subject to the provisions of the act." *U.S. Department of Agriculture Service and Regulatory Announcements*, No. 13 (1914), cited in Joint Comment of the Cigarette Manufacturers, Comment (Jan. 2, 1996), Vol. I, at 5 (emphasis added). *See* administrative record (AR) (Vol. 535 Ref. 96). Thus, to escape regulation under this interpretation of the Agency's authority, a tobacco product must not be labeled as a drug *and* must not be used as a drug. At the time this statement was issued, a drug was defined only as an article intended for the cure, mitigation, or prevention of disease, hence the limitation to use for "medicinal purposes." The definition was expanded in 1938 to include "articles intended to affect the structure or any function of the body."

prevent respiratory diseases were intended to treat or prevent disease). For many years, the existing evidence about the intended use of tobacco products was insufficient to conclude that tobacco manufacturers intended tobacco products as drugs or devices except when disease or structure-function claims were expressly made for the products. It is nevertheless indisputable that the Agency has consistently claimed jurisdiction over tobacco products when it has determined that they are intended to affect the structure or function of the body or to treat or prevent disease. What has changed is the nature of the evidence before the Agency on the question of whether cigarettes and smokeless tobacco are "intended to affect the structure or any function of the body."

B. A CHANGE IN THE EVIDENCE BEFORE THE AGENCY NOW ESTABLISHES "INTENT" TO AFFECT THE STRUCTURE AND FUNCTION OF THE BODY

1. Previous Agency Position and the Evidence on Which It Was Based

The Agency last considered whether to regulate tobacco products without disease or structure-function claims in connection with citizen petitions submitted in the late 1970's by Action on Smoking and Health (ASH) and others. The petitions sought to have FDA regulate all cigarettes as drugs or devices.

At the time that FDA responded to ASH's citizen petitions, the only evidence before the Agency was that presented by the petitioners: studies showing that nicotine produces some pharmacological effects in animals and humans and some very early evidence concerning the addictive properties of nicotine. The proposition that nicotine in cigarettes was addictive was not yet widely accepted in the scientific community, and the petition provided insufficient evidence to demonstrate addiction. Indeed, at the time the

petitions were submitted, no major public health organizations had concluded that nicotine is addictive. Because it was not yet recognized that nicotine is addictive, no data were available quantifying the proportion of smokers who were addicted and thus using cigarettes to satisfy their addiction.

The petitioners also presented no evidence that the tobacco companies knew of the pharmacological properties of nicotine, or that consumers used cigarettes for their pharmacological effects, or that the companies manipulated the levels of nicotine in cigarettes to satisfy smokers' need for nicotine. The petitions thus rested on evidence that nicotine has some pharmacological effects and the largely unsubstantiated assertion that many consumers used cigarettes for a drug purpose.

FDA concluded that although intended use could be established by evidence other than promotional claims, the evidence in the petitions was insufficient to find that the manufacturers of cigarettes "intended" these products to prevent, mitigate, or treat disease or to affect the structure or function of the body. For example, in response to the petition urging FDA to regulate filtered cigarettes as devices because they were intended to mitigate disease, the Agency said:

> *ASH* asserts that objective evidence other than manufacturers' claims can be material to a determination of intended use under the statutory definition, and that *National Nutritional Foods Ass'n* v. *Food and Drug Administration*, 504 F.2d 761 (2d Cir. 1974), *cert. denied*, 420 U.S. 946 (1975), is authority for this interpretation (Petition No. 2, p. 21). We agree. However, the court there held that the vendor's intent is the crucial element in the statutory definition and that objective evidence sufficient to pierce the manufacturer's subjective claims must be presented (504 F.2d at 789).
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> . . . [*National Nutritional Foods Ass'n* v. *Weinberger*, 512 F.2d 688 (2d Cir. 1975) and *National Nutritional Foods Ass'n* v. *Mathews*, 557 F.2d 325 (2d Cir. 1977)] support FDA's position that it is the intent of the manufacturers or vendors that objective evidence must establish and that

> evidence of consumer use can be one element of objective evidence to be weighed in determining if the intended purpose of a product subjects it to regulation under the Act. ASH has not established that consumers use attached cigarette filters for the prevention, mitigation, or treatment of disease to the extent necessary to allow FDA to impute the requisite intended uses to manufacturers or vendors.[1161]

ASH appealed the Agency's decision not to regulate cigarettes as drugs. In *ASH*, the Court of Appeals deferred to FDA's determination and concluded that the evidence on "intended use" was not sufficient to overrule the Agency's interpretation. *ASH v. Harris*, 655 F.2d 236 (D.C. Cir. 1980). The *ASH* court recognized both that FDA was permitted to modify its interpretation and that the Agency's new position would be accorded deference by the courts. *Id.* at 237, 242, n.10. The court expressly left open the possibility that at some point in the future FDA might appropriately determine that cigarettes did fall within the Agency's jurisdiction: "Nothing in this opinion should suggest that the Administration is irrevocably bound by any long-standing interpretation and representations thereof to the legislative branch. An administrative agency is clearly free to revise its interpretations." *Id.* at 242, n.10.

The *ASH* decision, moreover, by no means supports the proposition that the industry comments urge, namely, that evidence of intended use must be limited to manufacturers' drug claims. The *ASH* court held that a finding that tobacco products were intended to affect the structure or function of the body could be based on substantial consumer use evidence alone or in combination with other evidence of vendor intent. *Id.* at 239-240. Nor was it the Agency's position at the time of the *ASH* case that the

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[1161] Letter from Goyan JE to Banzhaf, III JF and Georgiades PN (Nov. 25, 1980), at 8-9. *See* AR (Vol. 28 Ref. 238).

intended use of cigarettes could be established only through a manufacturer's overt drug claims. As noted above, FDA's 1980 response to ASH on its petition urging FDA to regulate filtered cigarettes as devices expressly stated that objective evidence other than claims is relevant to establishing intended use. In addition, the brief filed by the Agency before the Court of Appeals repeatedly stated the Agency's formal legal position that the intended use of cigarettes could be established through manufacturer's representations *or* other objective evidence of intent.[1162] As stated in that brief, the petition denial was based on "*two* findings":

> (1) that there was no evidence in the record that manufacturers or vendors of cigarettes *represent* that cigarettes are intended to affect the structure or any function of the body; and (2) that there was no evidence in the record of any other sort that manufacturers or vendors of cigarettes *intend* that cigarettes affect the structure or any function of the body (Denial Letter at 4).[1163]

Thus, even at the time of the Agency's last decision on its jurisdiction over cigarettes, the Agency recognized that intended use could be established on the basis of objective evidence of intent other than manufacturers' claims. FDA concluded at that time that such other evidence had not been presented to the Agency.

2. New Evidence Supporting the Agency's Change in Position

In the years since FDA's decision on the ASH petitions, dramatic new evidence has become available on the issue of the intended use of cigarettes and smokeless tobacco. FDA has therefore reevaluated the issue of its jurisdiction over tobacco products and finds

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[1162] Brief for Appellees at 9 n.7, 27-28, 30, *Action on Smoking and Health v. Harris,* No. 79-1397, *reported at* 655 F.2d 236 (D.C. Cir. 1980). *See* AR (Vol. 504 Ref. 8918).

[1163] *Id.* at 30 (emphasis in original).

that the evidence now supports a determination that cigarettes and smokeless tobacco are intended to affect the structure and function of the body, regardless of whether drug claims are made for the products. FDA bases this determination on three important categories of evidence that have emerged since FDA last declined to exercise jurisdiction over tobacco products without claims: (1) the development of a scientific consensus, on the basis of overwhelming scientific evidence, that nicotine in cigarettes and smokeless tobacco is highly addictive and produces significant effects on the structure and function of the body, making it foreseeable to a reasonable tobacco manufacturer that its products will have pharmacological effects and be used for those effects by a substantial proportion of consumers; (2) scientific data establishing that the vast majority of consumers who use cigarettes and smokeless tobacco are addicted to them and use these products nearly exclusively to obtain the pharmacological effects of nicotine; and (3) newly disclosed evidence showing that tobacco companies have in mind that their products will be used by consumers for pharmacological purposes and have designed their products to affect the structure and function of the body. As described in section II., above, FDA believes that each category of evidence provides an independent basis on which to conclude that cigarettes and smokeless tobacco are intended to affect the structure and function of the body.

In the Jurisdictional Analysis and in section II., above, FDA describes at length the body of evidence now before it. The vast majority of that evidence—including evidence that predates FDA's denial of the *ASH* petitions but was not made public by the tobacco industry—was not available to FDA in 1980. Since 1980, the quality, quantity, and scope of the evidence regarding the intended use of cigarettes and smokeless tobacco have

increased and sharpened dramatically. As described below, the evidence on the addictive nature of nicotine and on manufacturers' research on, manipulation of, and control over nicotine levels has grown exponentially.

a. Since 1980, a Scientific Consensus Has Emerged That Nicotine Is Addictive and Has Other Significant Pharmacological Effects and Uses

As described in section II.A., above, evidence that the pharmacological effects and uses of cigarettes and smokeless tobacco are foreseeable in a significant proportion of consumers is a sufficient basis on which to find that cigarettes and smokeless tobacco are intended to affect the structure and function of the body. Since 1980, the last time that FDA considered whether cigarettes were intended to affect the structure or function of the body, evidence of nicotine's addictiveness and other significant pharmacological effects and uses has become widely known and thus foreseeable by the manufacturers.

Before 1980, no major public health organization had determined that nicotine was an addictive drug. Between 1980 and 1994, however, every leading scientific deliberative panel and organization with expertise in addiction concluded that nicotine is addictive or dependence-producing. These organizations include the American Psychiatric Association, in its *Diagnostic and Statistical Manual of Mental Disorders,* Third Edition (DSM-III); the World Health Organization; the American Medical Association; the American Psychological Association; the American Society of Addiction Medicine; the Royal Society of Canada; and the Medical Research Council in the United Kingdom. In 1986, the U.S. Surgeon General issued a report concluding for the first time that smokeless tobacco is addictive. And in 1988, the Surgeon General issued a landmark report concluding that nicotine in cigarettes is addictive.